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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,066	10/06/2000	Rama Ranganathan	UTSD:645US/MTG	2858

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Mark T. Garrett
FULBRIGHT & JAWORSKI L.L.P.
SUITE 2400
600 CONGRESS AVENUE
AUSTIN, TX 78701

EXAMINER	
CLOW, LORI A	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 03/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/684,066	RANGANATHAN ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2 January 2004 has been entered.

Claims 1-18 are pending. Claims 19-34 have been cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant has included amendments to the claims which delete the language "statistically significant" from the claims. Applicant further adds language to clarify that the conservation energy values will identify evolutionarily conserved amino acids, as supported in the specification, for example, at page 6. However, Applicant has failed to address arguments pertaining to the enablement rejection which are re-iterated below, for Applicant's convenience. Therefore, claims 1-18 remain rejected.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) and e) In order to practice the claimed invention one of skill in the art must be able to identify positions in a polymer by accessing data and identifying positions by use of said algorithm. However, the methods of claims 1-18 are not enabled as the claims and the specification are lacking critical steps and information required for the performance of said methods. One of skill in the art would not be able to perform the invention as claimed and the steps as presently recited would not result in obtaining the desired information from the methods.

For example, in claims 1 and 10, **what polymers are selected**, on what basis are they selected, and how are they aligned in a multiple sequence alignment? The specification, at page 6, indicates that proteins are polymers that can be used, but is **silent as to other polymers** amenable to the method. For instance, are polyacrylamide polymers able to be used in this method? How would such non-protein polymers be aligned? Could free energy calculations be performed? The specification, at page 16, indicates that only protein sequences can be aligned, but is completely devoid of information as to how any other type of polymer is to be selected and aligned. Further, the claims do not set forth that the polymers to be aligned are from a single protein family or from related proteins. There is no requirement for a base level of similarity for

the multiple sequence alignment such that one of ordinary skill in the art would be able to select appropriate sequences for use in this method. The specification, at page 17, indicates that "protein families" are used, but does not speak to how such families are correctly aligned.

Applicant has argued that they are not claiming the creation of a Multiple Sequence Alignment (MSA) and go on to explain in detail how a MSA would be performed. It is acknowledged that MSA techniques are **well known** in the art and that Applicant is not claiming a method to perform an MSA. Applicant is claiming the identification of positions in a polymer family. Again, Applicant has ignored the questions pertaining to the accession of data in terms of what polymers are utilized. Applicant does state that this method is applicable to **any** polymer, including drugs, chemical polymers etc. However, Applicant does not provide any specifics as to how this is performed and the specification is devoid of any information showing an alignment of chemical or other polymers and how these types of polymers would be used in said invention. The specification only points to a limited example using the PDZ **protein** family.

One would look to the art to practice the invention. However, the art does not describe the claimed methods and without said steps known, it is not possible to practice said invention without undue experimentation.

b) and c) The specification provides working examples of using the particular method to calculate free energy for PDZ domains (page 26 and 27) that are known to be a family of small, evolutionarily well-represented protein binding motifs (page 25). The energetic profile of the fold family was determined and the energetic coupling function was determined. No specific steps to do this are outlined in the examples.

d) The invention is drawn to multiple sequence alignments to identify free energy and significant positions.

f) The skill of those in the art of bioinformatics is high.

g) The art is unpredictable.

h) The claims are broad because they are drawn to methods with **all polymers** and methods with minimal processing steps.

The skilled practitioner would first turn to the instant specification for guidance to practice the claimed methods. However, the instant specification does not provide specific guidance to practice these embodiments. As such, the skilled practitioner would turn to the prior art for such guidance, however, the prior art does not teach these methods. Finally, said practitioner would turn to trial and error experimentation to determine the limits and steps required. Such represents undue experimentation.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (571) 272-0549.

MARJORIE MORAN
PATENT EXAMINER
Marjorie A. Moran
3/10/04

March 10, 2004

Lori A. Clow, Ph.D.
Art Unit 1631
Lori A. Clow